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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,287	10/01/2003	Richard Hochberg	Y03-076US	7077
7590 09/29/2005				
Henry D. Coleman 714 Colorado Avenue Bridgeport, CT 06605-1601				
			EXAMINER BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,287	HOCHBERG, RICHARD	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claim recites the reduction of the likelihood of the occurrence or recurrence of breast cancer and, thus, it contemplates the use of the claimed

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compounds for the prevention of breast cancer. However, (a) the art does not teach prevention of breast cancer and (b) there is no known method(s) for the determination of a person susceptible to said disease and, thus, in need of preventive treatment. The present specification lacks guidance and/or working examples of prevention/reduction of breast cancer or reduction of the recurrence of breast cancer as recited by the instant claim. Therefore, in order to practice the claimed invention, the skilled artisan would have to first search the prior art to find, if possible, a model for the determination of a person prone to breast cancer and, thus, in need of preventive treatment. The amount of experimentation necessary to make said determination is undue because of the lack of guidance and/or working examples in the present specification.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 5-9, 11, 12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the following reasons:

(a) Claim 1 recites the phrase "preferably, X is O". The term "preferably" renders the claim indefinite because it is unclear whether the limitation following said term is part of the claimed invention. It is suggested that the phrase "preferably, X is O," be deleted.

(b) Claims 2, 5, 8 and 11 recite R^3 and R^4 , however, R as defined by the instant claims does not recite R^3 and/or R^4 .

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(c) Claims 6 and 12 recite R^1 and R^2 , however, R as defined by the instant claims does not recite R^1 and/or R^2 .

(d) Claim 7 drawn to a pharmaceutical composition recites the optional addition of a carrier, additive or excipient. If a carrier, additive or excipient is not present in the composition what is? Therefore, the metes and bound of the instant claim is indefinite. It is suggested the term "optionally" be deleted.

(e) Claim 9 recites a compound but is dependent on a composition claim and, thus, the claim is indefinite. For the purpose of prior art rejection, it is assumed the claim should read "[t]he composition".

(f) Claim 17 recites "treating a breast cancer patient in need thereof **with an agent to which said cancer favorably responds**". It is unclear what is intended by the phrase "an agent to which said cancer favorably responds".

Double Patenting

5. Claims 10-12 are objected to under 37 CFR 1.75 as being a substantial duplicates of claims 4-6, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jelinkova et al.

Jelinkova et al. teach 11 β -methoxymethyl-17 α -ethinyl-1,3,5(10)-oestratiene-3,17 β -diol and its estrogenic activity (see the entire article, especially page 389, Abstract, 2nd paragraph; Tables 1 and 2 and figure 1, compound #3659). The compound and composition taught by the reference are encompassed by the instant claims.

8. Claims 1, 3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Agarwal et al.

Agarwal et al. teach various analogs of 17 β -estradiol, such as 11 β -(2-methoxyethyl)-1,3,5(10)-estratrien-3,17 β -diol and their effect on glucocorticoid action (see the attached Abstract). The compound and composition taught by the reference are encompassed by the instant claims.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jelinkova et al.

Jelinkova et al. teach 11 β -methoxymethyl-17 α -ethinyl-1,3,5(10)-oestratriene-3,17 β -diol and its estrogenic activity (see the entire article, especially page 389, Abstract, 2nd paragraph; Tables 1 and 2 and figure 1, compound #3659).

The instant claims differ from the reference by reciting the treatment of the symptoms of menopause. However, the art teaches the use of estrogenic compounds in the treatment of menopausal symptoms, reduction of the risk of cardiovascular disease and breast cancer (see for example, Goodman and Gilman, seventh edition, pages 1421-1423; US 6,268,361, Abstract; US 2001/0025051; section 0003; US 4,617,298, col. 3, lines 25-31). Therefore, the utilization of the compound of Jelinkova in the treatment of disorders as recited by the instant claims would have been prima facie obvious to the skilled artisan in the art at the time of the invention. The motivation is based on the teaching by Jelinkova et al. of the estrogenic property of 11 β -methoxymethyl-17 α -ethinyl-1,3,5(10)-estratrien-3,17 β -diol and the knowledge in the art

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of the utilization of estrogens in treatment of menopausal symptoms, breast cancer, reduction of the risk of cardiovascular disease etc.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
September 26, 2005